510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k052207

B. Purpose for Submission:

New device

C. Measurand:

Glucose

D. Type of Test:

Quantitative

E. Applicant:

Incline Medical, LLC

F. Proprietary and Established Names:

Accurex Glucose Test Strip

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1345 – Glucose test system

2. Classification:

   Class II

3. Product code:

   CGA, NBW

4. Panel:

   Chemistry (75)

H. Intended Use:

1. Intended use(s):

   The Accurex Glucose Test Strips for use with the following glucometers: OneTouch Basic, OneTouch II and OneTouch Profile meters, all manufactured by Lifescan, Inc.

   It is to be used for the quantitative measurement of glucose in fresh capillary whole blood. Glucose measurements are used as an aid to monitor the effectiveness of diabetes control.

2. Indication(s) for use:

   The Accurex Glucose Test Strip for use with the following glucometers: OneTouch Basic, OneTouch II and OneTouch Profile meters, all manufactured by Lifescan, Inc.

   It is to be used for the quantitative measurement of glucose in fresh capillary whole blood. Glucose measurements are used as an aid to monitor the effectiveness of diabetes control.

3. Special conditions for use statement(s):

   This device is for over-the-counter use.

   This device is for use with capillary whole blood from the fingertip only.

4. Special instrument requirements:

   This device requires use of Lifescan, Inc.'s One Touch Profile, One Touch II, or One Touch Basic meters.

I. Device Description:

The Accurex Glucose Test Strip is a generic replacement for the Lifescan One Touch Glucose Test Strip. The device is a white plastic strip with a test spot indicated by a red arrow on one side and a red hash on the backside. The strip's chemical composition includes glucose oxidase (Aspergillus niger), peroxidase (horseradish), color indicator, stabilizers and buffers. The strips are supplied in two vials, each containing 25 test strips and a desiccant. A vial of control solution (92.7% water, 0.06% glucose, 0.84% preservative, and 6.44% pigment) is also supplied with the test strips.

J. Substantial Equivalence Information:

1. Predicate device name(s):

One Touch Glucose Test Strip

2. Predicate 510(k) number(s):

   k923544

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	For use with the One Touch® Basic®, One Touch® Profile®, and One Touch® II Meters to check blood glucose levels	Same
Indications for Use	For the quantitative measurement of glucose in fresh capillary whole blood. Glucose measurements are used as an aid to monitor the effectiveness of diabetes control.	Same
Test Principle	Membrane technology employing glucose oxidase/peroxidase reaction	Same
Dimensions	0.6” W, 1.75” L	Same

Differences		
Item	Device	Predicate
Assay Range	3 – 600 mg/dL	0 – 600 mg/dL

K. Standard/Guidance Document Referenced (if applicable):

None referenced

L. Test Principle:

The Accurex Test Strip, used together with the One Touch® Basic®, One Touch® Profile®, and One Touch® II Meters, measures the blood glucose levels using a membrane technology that employs a glucose oxidase/peroxidase reaction. The user turns on the meter, enters the calibration code into the meter, removes a test strip from the vial and inserts it in the meter, and applies a fresh sample of whole blood to the test spot. The result is displayed on the One Touch meter.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Fifteen replicates from each of five glucose contrived whole blood samples were analyzed on the One Touch Basic wide screen meter. As a control, each whole blood sample was analyzed on the YSI clinical analyzer before and shortly after replicate testing. The results were as follows:

YSI	**Accurex**	
mg/dL	mg/dL	%CV
42	44	3.2
135	135	3.2
254	257	3.5
377	361	2.3
486	469	3.1

b. Linearity/assay reportable range:

The assay reportable range is 3 to 600 mg/dL.

The linearity of the test strips was determined by testing ten replicates each of five heparinized blood glucose levels contrived with glucose stock solution on five randomly selected One Touch Basic meters. The true glucose values were determined with the YSI 2300D clinical analyzer, with average levels of 6, 132, 304, 407, and 515 mg/dL.

The following regression resulted: $y = 0.95x + 0.46$, $r^2 = 0.99$. The average levels on the Accurex strips were 9.3, 121, 289, 394, and 489 mg/dL. All the data points reside within the A zone of the Clarke error grid.

An additional study to support linearity between 489 and 600 mg/dL and to include a sample between approximately 50-70 mg/dL was performed per FDA's request. As before, ten replicates each of two samples were tested. The average reference results were 67 and 573 mg/dL, which were similar to the average Accurex strip results of 67 and 563 mg/dL. The recalculated

regression including the additional data is as follows: y = 0.97 – 0.72, r^2 = 0.996.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

The Accurex Control Solution is an aqueous material containing d-glucose, preservatives, and pigment. The assigned glucose range is established in the bulk and filled solutions. The assigned glucose range is based on the values from single use vial testing data with a batch of strips run on ten One Touch meters. The upper limit is equal to the average glucose value + 3SD. The lower limit is equal to the average glucose value – 3SD. The labeled range is 71-105 mg/dL.

Accelerated and real time stability data were provided. Three lots of control solution are stored at 40ºC and 75% relative humidity (accelerated) and 25ºC and 50% relative humidity (real time) and tested at several time points. Average glucose values and %CVs were calculated for up to 34 weeks. Accelerated and real time data were adequate, with average glucose values within the assigned range and CVs less than 5%.

The sponsor recommends in their labeling a second, higher, level of control material that has been validated for use with this system.

d. *Detection limit:*

The minimum detection limit is 3 mg/dL. To evaluate low range sensitivity of the Accurex strip, one lot was tested with five One Touch Basic meters. Three replicates of four patient samples were run on each meter, and the results were compared to the YSI 2300D clinical analyzer. The reference values ranged from 3 to 46 mg/dL. Using the Accurex strips, the values ranged from 3 to 43 mg/dL. The following regression resulted: y = 0.95 + 0.16, r^2 = 0.99.

e. *Analytical specificity:*

Heparinized blood was first adjusted to a normal glucose level with a glucose stock solution. Then an aliquot of the resulting blood sample was spiked with various concentrations of commonly known interfering substances (endogenous and exogenous). The potential interference was evaluated with five randomly selected One Touch Basic meters.

No interference was observed with Gentisic, Acetaminophen, Ibuprofen, Salicylate, bilirubin, uric acid, Tolbutamide, Tolazamide, L-dopa, and lipids. The results showed that sodium fluoride causes a significant drop in glucose values at an elevated level. Therefore, tubes containing sodium fluoride or other forms of fluoride salts or conjugates are not appropriate for collection of

specimen to be used with this test. Strong antioxidants such as ascorbic acid also showed notable decreases in glucose values at high levels.

Hematocrit values between 30% and 55% do not interfere with the results of this assay.

f. Assay cut-off:

See "Detection limit" above.

2. Comparison studies:

a. Method comparison with predicate device:

See "Other clinical supportive data" below.

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

A clinical study was conducted to evaluate the performance of the Accurex Glucose Test Strip in comparison to the predicate device. One hundred and forty (140) subjects, with 1 month to 57 years of experience using a glucometer to monitor their glucose levels, participated in the study. Subjects were given a box of predicate strips, a box of Accurex strips, and two One Touch Basic glucometers (strips and glucometers included instructions) and instructed to perform testing with both strips. A capillary sample was also obtained by the clinic personnel to perform a reference assay using the YSI 2300D clinical analyzer. Subjects and a trained observer were asked to fill out a questionnaire recording the results they obtained and comments.

The results were as follows:

	Accurex	Predicate
# Patients	124	125
Correlation Coefficient (r)	0.98	0.96
Slope	0.96	0.89
Intercept	2.1 mg/dL	7.4 mg/dL

For the subject device, 7% of the samples were not included due to low blood sample, incorrect strip insertion or incorrect blood application. Three percent (3%) of the samples were not included due to low sample volume errors with the clinical analyzer.

4. Clinical cut-off**:**

   Not applicable

5. Expected values/Reference range:

   The expected whole blood glucose levels that the sponsor provides in the labeling for people without diabetes are based on literature.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.